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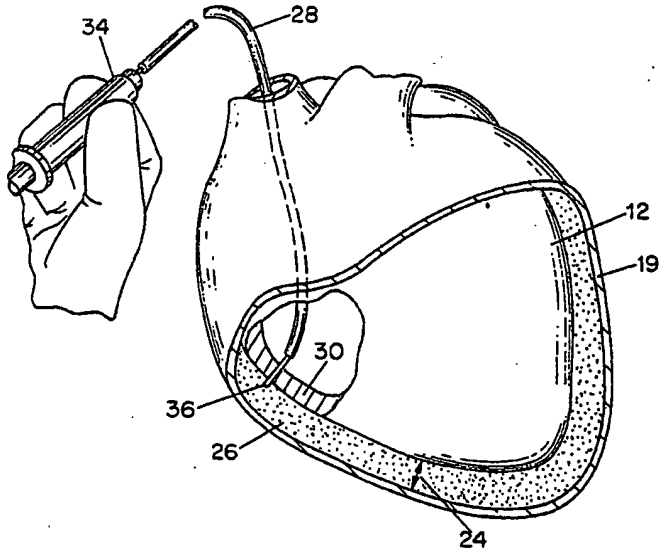
(54) Title: SYSTEM FOR ACCESS TO PERICARDIAL SPACE

(57) Abstract

A method and system for obtaining access to the pericardial space (24) of a mammal for performing medical operations therein is disclosed which includes means (34) for distending the pericardium from the heart by injecting a small volume of fluid into the pericardium. A needle (28) having a lumen therethrough is inserted from a sub-xiphoid or other percutaneous position into the body tissue until a tip thereof punctures the distended pericardium at a selected location. A guide wire (36) is inserted into the pericardium through the lumen of the needle (28) and while the guide wire remains in the pericardial space, the needle is removed. A sheath is introduced over the guide wire, with the aid of a dilator, and inserted into the tissue until one end thereof is positioned within the pericardium. The sheath provides an access channel into the intracardial space (24) for medical operations. Different medical operations could include insertion of pacemaker or defribillator electrodes, mapping devices, ablation devices, scopes or combinations thereof. Access can also be for diagnosis such as fluid and/or tissue sampling, and can also be for medication installation.



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# SYSTEM FOR ACCESS TO PERICARDIAL SPACE

## BACKGROUND OF THE INVENTION

### 1. Field of the Invention

The present invention relates generally to a method and system for pericutaneous access to the pericardial space for inserting diagnostic and/or therapeutic instruments including, but not limited to, pacemaker electrodes, defibrillation leads and electrodes, mapping devices, ablation devices, scopes, fluid or biopsy culturing devices, and/or medications, alone or in various combinations, including possibly a steering and affixing/anchoring device.

The pericardium is a membranous sac that encloses the heart. It consists of an outer layer of dense fibrous tissue and an inner serous layer, termed the epicardium, which directly surrounds the heart. Throughout the description and claims that follow, the phrase "within the pericardium" or "within the pericardial space" is used to mean any of the body tissue or fluid found inside of the dense outer layer of the pericardium, including the outer surface of the heart, but not including the interior of the heart.

The present invention is directed generally to a method and system for pericutaneous access to the pericardial space for diagnostic and therapeutic purposes. Specifically, one aspect of the present invention is directed to the implantation of defibrillator electrodes. In recent years a serious effort has been undertaken to implant automatic defibrillators in certain patients at high risk of experiencing ventricular fibrillation or other heart disorders. When fibrillation or related heart malfunctions are sensed by such devices, a large defibrillation shock is automatically delivered to the heart in an attempt to stimulate the heart back to a normal or near normal beating pattern. The advantage of such implanted devices is that the

life-saving defibrillation shocks are delivered without any undue delay, as would otherwise exist if external defibrillation pulses had to be delivered by paramedics (or other medical personnel) who were summoned to the aid of a heart-failing patient.

In order to minimize the energy of a defibrillation pulse, and thereby improve the efficacy of the defibrillation system, it is preferred that the defibrillation electrodes be in direct contact with the heart tissue. Further, it is generally preferred that the electrodes cover large and strategic areas of the heart, thereby allowing the delivered electrical energy to be efficiently distributed throughout the fibrillating region. Attempts at placing the defibrillating electrodes on the inside of the heart, either in the atria or the ventricles, or both, similar to stimulating electrodes used with pacemakers, have proven less than satisfactory.

Accordingly, implantable defibrillation electrodes are preferably placed around the exterior of the heart. Because of the large surface area covered by such electrodes, they are typically referred to as "patch electrodes", often resembling patches that are placed on the heart. Although there are some shortcomings associated with placement of defibrillation electrodes directly on the epicardial or endocardial surfaces, the advantages are overwhelming.

In order to make the best possible contact with the heart tissue, it is often desirable that implantable defibrillation electrodes be placed within the pericardium, or within the pericardial space. Unfortunately, however, pericardial placement of defibrillation leads is a dangerous and difficult procedure that has heretofore generally required traumatic and endangering surgery, usually open-chest surgery. Needless to say, not all patients are suitable candidates for open-chest surgery, and even for those that are, the risks, trauma, and danger associated with such surgery make this procedure of electrode placement less than ideal.

In an attempt to minimize the problems associated with open-chest surgery for the placement of epicardial defibrillation leads, it has been suggested in the art to implant epicardial defibrillation leads transvenously. Such an approach is described in U.S. Patent No. 4,884,567 issued December 5, 1989 entitled "Method For Transvenous Implantation of Objects into the Pericardial Space of Patients," jointly invented by the applicant named herein and Donald M. Cohen. This prior application, including the methods and leads described therein (hereafter referred to as the "transvenous implantation approach"), is hereby incorporated herein by reference. See also related U.S. Patent No. 4,946,457 issued August 7, 1990 entitled "Defibrillator System With Cardiac Lead and Method For Transvenous Implantation" in the name of the present applicant which is hereby incorporated herein by reference. See also U.S. Patent No. 4,991,578 issued February 12, 1991, entitled "Method and System for Implanting Self-Anchoring Epicardial Defibrillation Electrodes", which is hereby incorporated by reference.

In accordance with the transvenous implantation approach described in the first above-referenced prior patent, a guide wire and a catheter are inserted into the heart transvenously, with the aid of an introducer, as required. Once in the heart, the atrial lateral wall is punctured, making a hole therein, through which the non-deployed defibrillation electrode is inserted, thereby entering the pericardial space. The non-deployed electrode is further positioned within the pericardial space to a desired position, and then the electrode is deployed so as to better contact a larger surface area of the outside of the heart.

The transvenous implantation approach also suffers from several drawbacks. For one, a fairly good size hole must be made in the atrial wall, and the trauma and long term effects of such a hole are uncertain. Further, the approach is generally limited to an introducer not much larger than a Fr 14. (A FR 14 instrument is

approximately 4.7 millimeters in diameter.) Additionally, the introducer's path is somewhat tortuous, resulting in challenging lead placement. Moreover, once the lead is placed, the ensuing connection of the lead to the site of the implanted defibrillator is non-trivial.

From the venous location of the lead, the lead connector must then be tunneled to the defibrillator site, generally in the abdomen. These limitations place severe restrictions on the geometry and flexibility of the electrode and the deployment system. For small, easily deployed lead systems, the transvenous implantation approach offers a very viable alternative to open chest surgery, particularly if a long tunneled lead is not objectionable. However, in the event very large surface electrodes are desired, or if tunneling is undesirable, the transvenous approach is probably no more effective, and perhaps less effective, than a more direct surgical approach.

What is needed, therefore, is a method and system for obtaining access to the pericardial space for various diagnostic and therapeutic purposes, including placing defibrillation leads in the propitious pericardial space, that avoids the major problems associated with both the open-chest surgery approach and the transvenous access approach. The present invention advantageously addresses this need.

SUMMARY OF THE INVENTION

The disadvantages and limitations of the background art discussed above are overcome by the present invention. With this invention, a method and system for pericutaneous access to the pericardial space for inserting diagnostic and/or therapeutic instruments are provided.

The present invention is directed to the insertion of (1) pacemaker electrodes, (2) defibrillation lead implantation, (3) mapping devices, (4) ablation devices for ablating re-entry pathways by an energy source, including, but not limited to RF or radio frequency generators, lasers, DC (direct current shock) or cryoablation (freezing), (5) fiber optic or other scopes, (6) diagnostic devices, such as for culturing pericardial fluid or biopsy of the pericardial space for culture and tissue analysis, (7) medication installation, such as antibiotics to treat an infection, antifungal agents to treat a fungal illness, chemotherapeutic agents to treat a neoplastic process, or installation of an anti-inflammatory agent such as steroids to treat an inflammatory process, (8) combination devices such as a combination of pacing, mapping and defibrillation electrodes for a complex pacing, anti-tachycardia and defibrillation device, and (9) steering devices alone or in combination with one or more of the above-described devices, such as catheters, mapping devices and defibrillation devices, for steering and affixing/anchoring the implanted device either to the epicardial surface or to the pericardial surface.

Advantageously, the present invention recognizes that a small sub-xiphoid or other percutaneous access into the mediastinum (the space bounded by the two pleural membranes, the pericardium and the diaphragm) can be used to provide a direct access to the pericardium, through which an introducer can be placed.

Such a sub-xiphoid or other introducer can easily be twice the diameter of a subclavian venous introducer, yet its placement can

be less painful and cause less damage. Hence, this percutaneous direct access to the pericardial space is preferable over the transvenous implantation approach because it presumably (1) is easier to achieve, and (2) affords more latitude in the lead choice, placement and design, and (3) will entail less mortality and morbidity.

One of the most critical considerations of the method and system of the present invention lies in gaining direct percutaneous access to the pericardial space without puncturing or otherwise damaging the heart. This is because, in the absence of a pericardial effusion, any attempt to introduce a sharp object percutaneously with the intent of piercing the pericardium would almost certainly also invade the myocardium.

To address this concern, the present invention includes means for distending the pericardium from the heart by injecting a small volume of fluid into the pericardium, thus creating a pericardial effusion. This injection extends the pericardium away from the heart. A conventional needle having a lumen therethrough is then inserted from the desired percutaneous location into the body tissue until a tip thereof punctures the distended pericardium at a selected location.

Several means are available for the accurate detection of the moment that the needle tip enters the pericardium before it cuts the epicardium. Among the possibilities are (1) fluoroscopic guidance, (2) monitoring of the force resisting the needle advancement, (3) ECG recording using the needle as an electrode, and (4) pressure monitoring. Perhaps the simplest method may be the most precise and reliable. That is, the egress of the injected fluid through the needle lumen signals that the pericardial space has been entered and that further insertion of the needle can be stopped (else the needle may puncture the heart).

A guide wire is next inserted into the pericardium through the lumen of the needle, whereupon the needle may be removed. A suitable sheath or introducer is then placed over the guide wire and inserted into the tissue until a distal end thereof is positioned within the pericardium. The sheath provides an access channel for medical operations within the pericardium.

Where the medical operation is implantation of a defibrillation lead, the lead, with its electrode in a retracted position, is next inserted through the sheath or introducer until the electrode is likewise positioned within the pericardium, whereupon the electrode is deployed in order to make contact with a large area of tissue within the pericardium.

The preferred percutaneous position from which access to the pericardium is attempted in accordance with the present invention is a sub-xiphoid position. However, it is to be understood that other access paths to the pericardium from a percutaneous location could also be used, such as intercostal access.

The present invention is directed to a method of obtaining access to the intrapericardial space of a patient's heart, to perform at least one medical operation therein, the method comprising the steps of (a) distending the pericardium from the epicardium by injecting a small volume of fluid into the pericardium, so that pericardial effusion results; (b) percutaneously perforating the pericardium by advancing a pericardium perforation device having a lumen therethrough towards the distended pericardium until the fluid flows out of the lumen, thereby indicating that the pericardium wall has been perforated; (c) inserting a guide wire into the pericardium through the lumen of the perforation device until a distal end thereof is positioned within the pericardium; (d) enlarging perforated opening in the pericardium by inserting a dilator over the guide wire and into the tissue; and (e) introducing a sheath over the guide wire into the enlarged perforated opening to create an access channel through the sheath into the intracardial space for a medical operation.

The present invention also includes a method of implanting defibrillation leads within the pericardial space of a mammal that includes the following steps: (a) distending the pericardium; (b) inserting guide means into the distended pericardium from a desired percutaneous position, such as a sub-xiphoid position; (c) inserting the defibrillation lead(s) into the pericardium following these guide means, where following the guide means may include inserting the lead within the guide means or over the guide means, or where the guide means may include two elements and the lead is inserted over one and within the other; and (d) tunneling the body of the defibrillation lead to a desired tissue location, whereat it may be connected to a desired defibrillation device.

Further, the present invention includes a method of positioning defibrillation leads within the pericardium of a mammal. The defibrillation lead(s) used with such a method preferably has a deployable distal electrode means for selectively placing an electrode in contact with a large tissue area when the electrode is deployed, and for selectively maintaining the electrode in a retracted or non-deployed position when the electrode is being inserted through a narrow opening.

This method of positioning includes the steps of: (a) injecting a fluid between the heart and the pericardium, thereby extending the pericardium away from the heart; (b) percutaneously, e.g., sub-xiphoidally, inserting guide means into the extended pericardium to a desired tissue contact location; (c) inserting the electrode, in its retracted position, within the pericardium by following the guide means; and (d) deploying the electrode within the pericardium, thereby making contact with a large tissue area at the desired tissue contact location within the pericardial space.

Further, the present invention may be characterized as a system for implanting one or more defibrillation leads in a mammal, such as a human, the mammal having a heart surrounded by a

pericardium. The defibrillation lead(s) used in such a system preferably has a deployable distal electrode that selectively assumes a retracted or extended position, the retracted position being adapted to promote the positioning of the distal electrode without having the distal electrode becoming entangled with body tissue, and the extended position being adapted to promote contact with body tissue over a large surface area.

However, it is to be emphasized that the implanting system works equally well with non-deployable electrodes. This implanting system includes: means for injecting a fluid between the heart and the pericardium, thereby extending the pericardium away from the heart; means for percutaneously inserting a guide means into the extended pericardium; sheath means for directing a sheath introducer into the pericardium over the guide means; insertion means for inserting the defibrillation lead, with its deployable distal electrode in its retracted position, into the pericardium through the sheath; and deployment means for extending the distal electrode to its extended position once it is positioned as desired within the pericardium.

The present invention is further characterized as a defibrillation lead system that includes: a sheath; means for percutaneously, e.g., sub-xiphoidally, inserting a distal end of the sheath into the pericardial space surrounding the heart; a defibrillation lead having at least one distal electrode, the defibrillation lead being of a size that allows it to be slidably inserted through the sheath until the distal electrode(s) resides within the pericardial space; and means for anchoring the distal electrode to a desired location within the pericardial space.

As will be evident from the description that follows, it is a feature of the present invention to provide a simple, safe and efficacious method and system of, providing access to the pericardial space for any one of a number of medical applications, including, but not limited to, insertion of pacemaker electrodes, defibrillator electrodes, mapping devices,

ablation devices, scopes or combinations thereof. Access can also be for diagnosis is such as fluid and/or tissue sampling, and can also be for medication installation.

It is another feature of the invention to provide such a method of access to the pericardial space that is less traumatic and dangerous than prior methods used for this purpose, such as open-chest surgery or transvenous techniques.

It is yet another feature of the invention to provide a flexible implantation method and system that allows a wide range of different types and sizes of devices to be introduced into the pericardial space.

DESCRIPTION OF THE DRAWINGS

These and other advantages of the present invention are best understood with reference to the drawings, in which:

FIG. 1 is a simplified diagram of a mammalian heart surrounded by a pericardium, and further shows a defibrillation electrode positioned therein and connected to an implantable defibrillation device;

FIG. 2A is a simplified diagram of the heart of FIG. 1 prior to placement of the electrode in the pericardial space;

FIG. 2B is a diagram as in FIG. 2A illustrating a distended pericardium resulting from injecting a fluid into the pericardial space through a fixation catheter that has been attached transvenously to the interior of the atrial wall;

FIG. 3A is a schematic perspective view of the fixation catheter of FIG. 2B prior to its attachment to the atrial wall;

FIG. 3B is a schematic perspective view, shown partially in cross section, showing the fixation catheter of FIG. 2B after its attachment to the atrial wall, and further illustrating a J-tip guide wire puncturing the atrial wall to form a hole through which the fluid used to distend the pericardium may be injected;

FIG. 4 is a simplified schematic drawing illustrating the manner of making sub-xiphoid access with a needle to the pericardium;

FIG. 5A is an expanded view of the sub-xiphoidally inserted needle tip of FIG. 4 as the needle tip just makes contact with the pericardial wall;

FIG. 5B is a view as in FIG. 5A after the needle tip has punctured the pericardial wall, and further illustrates the fluid in the pericardial space egressing via the lumen in the needle;

FIG. 6A is a view as in FIG. 5B further illustrating a guide wire or stylet inserted through the lumen of the needle into the pericardial space;

FIG. 6B is a view as in FIG. 6A further depicting a catheter inserted into the pericardial space over the needle and guide wire; and

FIG. 6C is an elevated view of the distal tip of an expanding pleated sheath or catheter that may optionally be used to gain access into the pericardial space.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

The following description is of the best presently contemplated mode of practicing the invention. This description is not to be taken in a limiting sense but is made merely for the purpose of describing the general principles of the preferred embodiment of the invention. The scope of the invention should be ascertained with reference to the appended claims.

At the outset, it is noted that the drawings used herein are not intended to be fully detailed representations of the physiological makeup of a mammalian heart and its surrounding pericardium, or of any other part or tissue location of the mammal. Rather, all of the drawings are presented in a very simplified format in order to emphasize the main features and steps of the invention. Most physiological detail has been omitted for clarity. However, it also must be emphasized that the drawings have been selected and designed to provide sufficient detail to enable one skilled in the cardiac medical surgery and implantation arts to readily carry out and practice the present invention.

The invention in its broad sense is directed to a method for obtaining access to the pericardium. In accordance with the present invention, the method for obtaining access to the pericardium may include the following steps:

1. Percutaneous entry into the venous system of a patient is obtained while the patient is under local anesthesia. This entry could be obtained by accessing the right subclavian vein, left subclavian vein, left or right internal or external jugular veins, left or right cephalic veins, or left or right femoral veins. Access is made into the venous system with a needle, and then a guide wire is passed into the venous system and a sheath with a dilator is passed over the wire leaving the sheath in place in the venous system to allow ready access.

2. A guiding or steering catheter is then passed through the sheath into the venous system and into the patient's right atrium or right ventricle.

3. An active fixation catheter with a helical coil is then passed through the steering catheter. The steering catheter is then positioned against the free wall of the right atrium which could include the right lateral wall, anterior wall or right atrial appendage. The active fixation catheter is then advanced against the wall and turned to anchor the wall. An alternate free wall which could be used for anchoring purposes is the ventricular wall.

4. A guide wire is then passed through the active fixation catheter until it comes in contact with the anchored myocardium. The guide wire has a tip and the wire includes means to selectively make the tip either stiff or flexible. A 0.035 inch diameter wire could be used. The guide wire is then stiffened, and, while retracting the atrial wall or ventricular wall with the active fixation device, one applies positive pressure until perforation of the wall occurs. As soon as perforation occurs, one manipulates the stiffening device to make the guide wire tip flexible so that it can be advanced into the pericardial space. A small caliber infusion catheter can then be advanced over the guide wire and through the active fixation catheter until it passes through the exit point of the atrial or ventricular wall and into the pericardial space. Instead of using a guide wire in combination with and to guide an infusion catheter, a guide wire having a small lumen can be used alone without having to use a separate infusion catheter. Such a guide wire, also known as an infusion wire, is currently available, and would allow fluid to be infused through the guide wire.

5. After either an infusion catheter or infusion wire is in the pericardial space, fluid such as saline or other medically acceptable fluid is infused through said device into the pericardial space. The patient's blood pressure is monitored. If a small drop in blood pressure occurs (indicating tamponade is impending), infusion will be stopped. Pericardial infusion may be verified by echocardiogram, or the fluid may have some radio-opaque dye to enable visualization on an x-ray. The infusion of the fluid creates a protective layer between the pericardium and epicardium.

6. Pericutaneous entry may then be achieved from the subziphoid approach by the following steps:

(a) Clearing the area of insertion in the subziphoid area with antiseptic solution and then infiltrating with xylocaine or local anesthesia.

(b) Inserting a perforation device with a lumen such as a long 18-gauge needle pericutaneously through the anesthetized area aiming under the rib cage and directing towards the left shoulder. As the needle is advanced, the syringe is aspirated or negative pressure is applied. When the needle perforates the pericardial space, infused solution in the pericardial space will be withdrawn through the needle (because of the negative pressure in the needle) indicating entry into the pericardial space. Advancement of the needle is immediately terminated to avoid puncturing of the of the heart.

(c) Advancing a guide wire through the needle into the pericardial space.

(d) Passing a dilator over the guide wire to create a track from the subziphoid area through the chest wall into the pericardial space.

(e) Passing a sheath over the guide wire into the region leaving the sheath in place to provide a channel for direct access.

(f) If necessary or desirable, a second access or entry point for a pericardiscope or other instrument for maneuvering or stapling the device to be inserted is created using the steps (a)-(e) above.

(g) After access to the pericardial space is obtained, any one of various diagnostic and/or therapeutic procedures can be performed by passing appropriate instruments, medicines, tissue samples, etc., through the sheath or sheaths into the pericardial space.

(h) After pericutaneous access to the pericardial space has been achieved from the sub-ziphoid area with a sheath, the infusion catheter or infusion guide wire is withdrawn through the myocardial puncture site. The active fixation catheter remains attached for another 10-20 minutes to allow sufficient time for thrombus formation at the puncture site to prevent bleeding into the pericardium.

(i) Removing the active fixation coil by rotating it counterclockwise to release the myocardial wall (either the right atrial wall or right myocardial wall), and withdrawing the fixation catheter, including other assemblies possibly forming a part thereof (including any steering assembly), from the patient's venous system.

In tests using experimental animals, little or no bleeding into the pericardium occurred after removal of the active fixation catheter. However, if any bleeding should occur, the physician still has access to the pericardial space through the sub-ziphoid sheath allowing aspiration of any blood to prevent tamponade.

While the guiding catheter, active fixation catheter and infusion wire may have been referred to above as separate devices, these devices could be combined into one assembly.

While the invention in its broader sense is directed to accessing the pericardium for any one or more of different medical purposes, the invention will be described in a specific mode of implanting a defibrillation electrode.

Referring first to FIG. 1, a simplified diagram of a mammalian heart 12 surrounded by a pericardium 14 is illustrated in a simplified format. As an example only, the mammal illustrated in FIG. 1 is a human 10. Further, for clarity, a portion of the pericardium 14 is shown cutaway in order to better illustrate the heart 12 inside of the pericardium. In accordance with the teachings of the present invention, a defibrillation electrode 16, connected to the distal end of a defibrillation lead 18, is passed through an opening 17 within the pericardial wall 19 and positioned within the pericardial space (that space between the exterior heart surface and the interior of the pericardial wall).

Advantageously, this defibrillation lead 18 is directed to the heart from a sub-xiphoid location, i.e., from a location below or underneath the lower end of the xiphoid process below the sternum or breast bone 20. The proximal end of the defibrillation electrode 18 is connected to a suitable defibrillation device 22. The defibrillation device 22 and the lead 18 are preferably implanted within the human 10 using conventional techniques known in the art, i.e., forming a suitable "pocket" within the flesh of the human where the device may be located, and tunneling the lead 18 from the pocket to its sub-xiphoid channel into the pericardial space. As will be apparent from the description that follows, the present invention is directed to a method and system for effectuating and using a sub-xiphoid implantation of a defibrillation electrode, such as is shown in FIG. 1.

In accordance with a particular method of the present invention, a defibrillation lead is implanted sub-xiphoidally within the pericardial space as follows:

1. The right atrial wall of the heart is perforated with a small opening using a suitable fixation catheter and guide wire, inserted into the heart transvenously. The perforation is limited to the atrial wall and does not traverse the pericardium. This perforation provides access into the pericardial space. Advantageously, this perforation in the atrial wall remains very small (compared to the large perforation required for the transvenous implantation approach described in the first referenced patent above), is used for only a very short period of time, and completely heals over after use.

2. A small volume of fluid (e.g., 25-75 cc for humans), such as saline or renografin, is infused into the pericardial space through the fixation catheter and the opening in the atrial wall. This is done for the purpose of distending the pericardial wall away from the heart in order to facilitate a sub-xiphoid entry into the pericardial space. The volume of fluid infused should be less than the amount that would cause cardiac tamponade and dysfunction.

3. From a sub-xiphoid location, a cardiac needle is inserted into the distended pericardium. Advantageously, the fluid squirts out of the needle lumen to indicate that the needle advancement should be halted before perforating the heart.

4. A guide wire is inserted through the needle into the pericardial space.

5. The needle is removed and a sheath/dilator introducer is inserted into the pericardial space over the guide wire. The opening in the pericardial wall made by the needle is enlarged as required in order to allow the larger introducer to fit there within.

6. The distal end of a defibrillation lead is inserted into the pericardium over the guide wire and within the sheath. (Alternatively, at the discretion of the physician, the guide

wire may be removed after sheath placement, before lead placement.) This distal end preferably includes a deployable defibrillation electrode having a large area electrode in a retracted position.

7. Once within the pericardial space, the electrode of the defibrillation lead is positioned as desired and the electrode is deployed. Further, the deployed electrode is anchored, as required.

8. Finally, the body of the defibrillation lead is tunneled through body tissue, using conventional methods, to a desired implant location. At this location, a suitable defibrillation device is connected to the lead and implanted, using conventional implant techniques and methods known in the art.

Some of the above steps associated with the method of the present invention are considered conventional in the medical implant art, and will not be described further. Other steps require further explanation, as set forth below.

One of the more difficult aspects of the present invention is gaining sub-xiphoid entry into the pericardial space without puncturing the heart. With reference to FIG. 2A, for example, an expanded simplified view of the heart 12 is shown inside of the pericardium 14, the pericardium being shown in cutaway fashion so as to clearly illustrate the pericardial wall 19 and the space between the pericardial wall and the heart, or the pericardial space 24. This space is shown greatly exaggerated in FIG. 2A for emphasis.

It is not uncommon for the pericardial space 24 to be very narrow in a normal heart, with the inside of the pericardial wall touching, or nearly touching, the exterior of the heart. Hence, it is very difficult to puncture or perforate the pericardial wall 19 without also damaging the myocardium, at the least, or causing tamponade and impending mortality at the worst.

In order to overcome this difficulty, the present invention contemplates filling the pericardial space with a fluid 26, thereby extending the pericardial wall 19 away from the heart, as shown in FIG. 2B. (In FIG. 2B, the fluid 26 is symbolically represented by small dots placed within the pericardial space 24.) The fluid 26 is injected into the pericardial space 24 through a fixation catheter 28 that is inserted transvenously, e.g., through the jugular or subclavian vein, into the heart and affixed to the interior of the right atrial wall 30.

Once the catheter 28 is secured to the atrial wall 30, a small opening is made in the atrial wall 30 (described below in connection with FIGS. 3A and 3B). This need not be a large opening, and is preferably made with the tip of a suitable stylet or guide wire 36. Once the opening is made, suitable infusion means, such as a hand-held syringe 34, are used to selectively force the desired volume of fluid 26 through the catheter 28 and into the pericardial space 24. The use of a hemostasis valve on the proximal end of the fixation catheter 28 may optionally be used during this process.

It is noted that fixation catheters are known in the art, as is the method of transvenously inserting a catheter or lead into the heart, as guided by a stylet or guide wire placed inside of the catheter or lead. In pacemaker art, for example, it is a very common practice to transvenously insert pacing leads into desired locations, either within the atrium, the ventricle, or both, of a heart using a stylet to guide placement of the distal tip of the lead.

The distal end of the fixation catheter 28 is shown in FIG. 3A prior to fixation thereof to the atrial wall 30. The catheter includes a main body portion 38 made from a tube of silicone rubber (or other body compatible substance) having a helical tip 40 connected to the distal end. The helical tip 40 is designed to be screwed into body tissue by rotation of the catheter.

Typically, the helical tip is made from a wire, such as stainless steel wire (or other safe implantable material).

In order to provide adequate torsional stiffness for the catheter 28, yet at the same time to allow suitable flexibility for the catheter, the wire from which the helical tip is made may extend, in a helical wound manner, along the entire length of the catheter 28. During transvenous insertion, the helical tip may be retracted within the tubular wall 38. When the distal end of the catheter tube 38 is positioned at a desired fixation location, as guided by the stylet 36, the helical tip 40 is extended as the entire catheter is rotated, as indicated by the arrow 42, so as to screw the helical tip 40 into the atrial wall 30.

Once the catheter 28 is anchored into the atrial wall 30, a small hole or opening 44 is punched or perforated through the atrial wall using the tip of the stylet wire 36 or equivalent device. One such equivalent puncturing device is shown in FIG. 3, where a J-tip stylet wire 36' is shown inserted through the catheter 28 and through the atrial wall 30.

The preferred puncturing technique is to retract the fixation catheter 28 in the direction shown by the arrow 46 while simultaneously advancing the guide wire 36', so that the atrial wall 30 is separated from the pericardial wall 19, thereby increasing the width of the pericardial space 24 as the guide wire 36' is punctured through the atrial wall 30. This minimizes the likelihood of having the guide wire 36' puncture through both the atrial wall 30 and the pericardial wall 19.

Once the pericardium 14 has been bloated with a fluid, or any other suitable technique is used to distend the pericardium 14 from the heart 12, the next step is to insert a needle 50 into the pericardium from a sub-xiphoid location, as shown in FIG. 4. The goal is to puncture the inflated pericardium with the needle 50, but to avoid having the needle puncture the heart, as is

commonly done in the art to relieve cardiac tamponade. This requires a controlled insertion depth of the needle, made easier by simply monitoring the lumen of the needle for egress of the fluid 26 with which the pericardium has been filled.

As illustrated in FIG. 4, application of suction, as with a syringe, while advancing the needle may aid in detecting the presence of the needle tip in the pericardium. Further, some instrumentation can make this sub-xiphoid entry more controlled. It is noted that pericardial drainage is a relatively common and safe procedure for the treatment of patients with pericardial effusions, and the incidence of cardiac perforation is very small.

Further, because of chest movement during respiration, the pericardium may move while pericardial access is being attempted. Hence, it is preferred that a perforation mechanism be used that perforates the pericardium, and then becomes impotent (i.e., unable to further puncture the cardiac wall or any other tissue).

Referring next to FIGS. 5A and 5B, the actual perforation of the pericardium 14 will be described. The needle 50 is advanced through the sub-xiphoid tissue into the mediastinum and abutted against the pericardial wall 19, as shown in FIG. 5A. This needle is preferably a blunt metal hypodermic needle tube of a type commonly known in the art. As a tube, the needle has a hole, or lumen, passing longitudinally therethrough. A rod 52 is initially included within the lumen to prevent coring of tissue as the needle is inserted. Neither the needle 50 nor the rod 52 are extremely sharp. At the distal tip, both are slightly angled, but blunt.

At the point where they abut against the pericardium, the pericardium is stretched, but (due to the nature of the pericardial tissue) is not easily perforated. At this point the rod 52 is withdrawn from the needle tube 50 and the needle 50 is further inserted in order to punch through the pericardial wall

19. Once perforation occurs, as illustrated in FIG. 5B, the fluid 26 within the pericardial space 26 begins to egress through the lumen of the needle 50, as illustrated by the arrows 54.

If the lumen of the needle or tube 50 is sufficiently large, it can function as the introducer through which other devices can be passed into the pericardial space 24, including the defibrillation lead 18. However, often a larger introducer is needed and/or a softer (polymeric) introducer is desired. In such instances, a method of enlarging the hole through the pericardial wall and introducing a sheath therein must be employed.

One such method is illustrated in FIGS. 6A and 6B. Referring first to FIG. 6A, a guide wire, having a blunt tip 66 is inserted through the lumen of the needle 50 so that the blunt tip is within the pericardial space 24. Then, depending upon the type and size of sheath to be inserted, the needle 50 may be withdrawn and a suitable sheath 68 may be inserted over a dilator which slides over the guide wire 64. Alternatively, the sheath 68 may be inserted over both the needle 50 and guide wire 64, as shown in FIG. 6B, in which case the needle would not be withdrawn until after the distal end of the sheath has been inserted into the pericardial space 24. The guide wire may then be used to assist in introducing the defibrillation lead 18 into the pericardial space, as well as to assist in the positioning of the defibrillation electrode to a desired location within the pericardial space.

In general, conventional techniques may be used for inserting the sheath 68 into the pericardium 14. In a preferred introduction, the sheath 58 is simply inserted over the needle 50 and, through the application of a gentle longitudinal force on the sheath, the sheath is pushed through the hole, thereby dilating the hole in the pericardial wall so as to enlarge it sufficiently to allow introduction of the sheath. However, despite the fact that the pericardium is attached to the diaphragm, pushing against the

pericardium (in order to force the sheath thereinto) may prove difficult without damaging the heart.

Accordingly, other possibilities for enlarging the pericardial hole may be considered. These possibilities include: (1) using an angioplasty style balloon across the hole; (2) inserting a deflated balloon into the pericardial space, inflating the balloon, and retracting the inflated balloon through the hole; (3) using a mechanical device that enlarges the hole by cutting it larger; (4) using a mechanical device that enlarges the hole by stretching it using a biopsy forceps technique, similar to a blunt dissection; (5) using a mechanical device that enlarges the hole by stretching it using an expanding mini collet; or (6) using a pleated sheath that can be inserted with its pleat(s) in a folded position, thereby providing a small diameter sheath, and then enlarged to provide a large diameter sheath, stretching the hole as it enlarges.

The blunt dissection approach mentioned above (item 3) contemplates the use of a narrow, blunt tapered pair (or multiplicity) of jaws, pivotally mounted for closing or expanding. These jaws are placed in the hole in their closed position, then spread apart to separate (or tear) the layers of tissue apart.

The pleated sheath approach mentioned above (item 6) contemplates the use of a sheath 68' having an expanding diameter. An elevated view of the distal end of such a sheath is illustrated in FIG. 6C. The sheath 68' includes at least one pleat 69 along the length thereof. This pleat simply comprises an integral section of the wall of the sheath that is folded into the interior of the sheath. Typically, the sheath 68' including its pleat 69 is made from a suitable biocompatible elastically expandable substance, such as silicone rubber.

A tip 71 at the distal end of the sheath 68' is tapered from a narrow tip portion 73 to a larger end portion 75. As seen in

FIG. 6C, the tip 71 resembles a conical arrow head. (Note that the sheath 68' shown in FIG. 6C is shown partially expanded, intermediate its most narrow diameter position, wherein the pleat 69 is completely folded inside of the sheath body, and its widest diameter position, where the pleat 69 is not folded in to the interior of the sheath body at all.)

To enlarge the small hole in the pericardial wall, the sheath 68' is inserted over the guide wire and needle with the pleat(s) 69 completely folded into the sheath body, i.e., in its most narrow diameter position. The small portion of the tip 73 is inserted into the pericardial hole. The sheath is then expanded, using conventional means, as a gentle longitudinal force is exerted on the sheath in order to force the tip 71 deeper into the pericardial hole. As the sheath expands, and as the tip moves deeper into the hole, the hole is expanded by the increasingly wider tip 71. The sheath may then be fully expanded and inserted well into the pericardial space 24.

With the guide wire in place and the pericardial hole enlarged (and assuming a pleated sheath 68' is not already in place as above described), the sheath 68 is inserted well into the pericardial space 24 (FIG. 6B). Over the guide wire 64 and within the sheath 68, a suitable defibrillation electrode is advanced. It is noted that the preferred defibrillation electrode is deployable, having its electrode(s) in a retracted position while being inserted through the sheath.

However, it should be emphasized that this technique for sub-xiphoidally inserting a defibrillation lead would also have application to smaller, non-deployable defibrillation leads, of the type known in the art. Advantageously, a plurality of such leads and/or electrodes can be positioned in a desired configuration, such as an orthogonal configuration, within the pericardial space using this technique.

Some possible deployable electrode configurations that lend themselves for use with the present invention are disclosed in the ~~first~~ above-referenced patent describing the transvenous implantation approach.

One of the advantages of the present invention resides in the manner in which the electrode 16 is anchored to a desired location within the pericardial space. One such anchoring technique is to use passive sclerosing pads or pericardioscope guided stapling or suturing. Another, perhaps better approach is to use an adhesive that is carried into the pericardial space on the non-deployed electrode. However, no biocompatible adhesives that may be applied to a beating heart are known to the applicant. However, the desired adhesion effect can advantageously be achieved by stimulating a fibrosis attachment site.

It is to be understood that the present invention also encompasses placement and anchoring of the electrode(s) to the epicardium or pleural sac, as such is also considered as being within the pericardium for purposes of the present invention.

Further, as has previously been mentioned, the techniques of placing and anchoring a defibrillation electrode as taught herein also find application when other approaches to access the heart, besides a sub-xiphoid approach, are utilized. For example, an intercostal access to the heart could be used.

It is also to be understood that the defibrillation electrode(s) could be positioned and/or anchored extra-pericardially, in accordance with the teachings of the present invention, using sub-xiphoid, intercoastal, or other access techniques.

The problem of perforating through one wall of tissue that is adjacent another wall of tissue raises the possibility that the puncturing mechanism or device may, unless it is controlled, puncture through both walls of tissue. Where sub-xiphoid or other

access into the pericardial space is being attempted, a puncture through the pericardial wall is essential; but a puncture through the myocardial wall into the heart (either atrium or ventricle) is to be avoided. The best puncture method to use in a given situation depends largely upon the particular patient and his or her unique physiological makeup, the skill of the person performing the operation, and the availability of special equipment and tools.

The simplest, and perhaps the most effective, puncture technique is described above. Other possible puncture devices, techniques and methods will occur to those skilled in the art. Many devices and methods were originally conceived for the purpose of puncturing through the atrial lateral wall from within the heart (as accessed transvenously) without puncturing through the pericardial wall. However, these devices, methods and techniques are generally also applicable to puncturing through the pericardial wall from a sub-xiphoid or other percutaneous position without puncturing through the myocardial tissue of the heart.

Instead of the methods discussed herein for affixing or anchoring the device either to the pericardium or to the epicardial surface once the proper position has been achieved and the proper function has been verified in that location, other methods could be used. One such method may be to use a steering device with or without fiber optics which would allow positioning of an electrode device or the like anywhere within the pericardium and than stapling the device to the pericardium through a predetermined stapling ring. The steering and stapling means can be removed, leaving a pericardial catheter in place. Such a means could be a thoracoscope type device, which could be more aptly named a pericardioscope. Such a device would enable the physician to visualize the pericardial surface and position the device at any point on the surface for biopsy or for positioning a catheter and affixing it with a staple or other mechanical means.

When using the method of the present invention to implant defibrillator electrodes, for example, it may be desirable to employ ~~a~~ steering means in order to aid guiding the catheter to the desired location. Such means could include a hydraulically operated chamber in the wall of the catheter making it flex or contract depending on the hydraulic pressure. Another means could be a channel within the catheter into which various pre-shaped steering devices could be inserted for positioning on any area of the heart. Yet another means could be a separate device which could be inserted along with the catheter through the same sheath or through a separate entry point, which may or may not employ fiber optics for visualization, but could provide the steering capability for moving a device into a necessary or desired position.

Although an exemplary embodiment of the present invention has been shown and described, it will be apparent to those having ordinary skill in the art that a number of changes, modifications, or alterations to the invention as described herein may be made, none of which depart from the spirit or scope of the present invention. All such changes, modifications, and alterations should therefore be seen as within the scope of the present invention.

What is claimed is:

1. A method of obtaining access to the intrapericardial space of a patient's heart, to perform at least one medical operation therein, the method comprising the steps of:

(a) distending the pericardium from the epicardium by injecting a small volume of fluid into the pericardium, so that pericardial effusion results;

(b) percutaneously perforating the pericardium by advancing a pericardium perforation device having a lumen therethrough towards the distended pericardium until the fluid flows out of the lumen, thereby indicating that the pericardium wall has been perforated;

(c) inserting a guide wire into the pericardium through the lumen of the perforation device until a distal end thereof is positioned within the pericardium;

(d) enlarging the perforated opening in the pericardium by inserting a dilator over the guide wire and into the tissue; and

(e) introducing a sheath over the guide wire into the enlarged perforated opening to create an access channel through the sheath into the intracardial space for a medical operation.

2. The method of claim 1, wherein the step of distending the pericardium comprises:

(a) transvenously attaching a catheter to a wall of one of the right atrium or ventrical;

(b) advancing a guide wire having a tip through the catheter until the tip contacts the wall;

(c) puncturing the wall with tip of the guide wire; and

(d) infusing the volume of fluid through the catheter into the pericardium.

3. The method of claim 2, wherein the guide wire comprises means for selectively rendering the guide wire relatively stiff or flexible, wherein the guide wire is made relatively stiff during puncturing of the wall, and wherein the guide wire is made relatively flexible after perforation and the guide wire tip is advanced into the pericardial space.

4. The method of claim 1, wherein the step of distending comprises advancing a puncturing-infuser device having a lumen therethrough through a wall of one of the right atrium or ventrical and then infusing the small volume of fluid through the lumen into the pericardium.

5. The method of claim 1, wherein the puncturing-infuser device comprises a guide wire having a lumen therethrough.

6. The method of claim 1, wherein the step of distending further comprises injecting fluid having radio-opaque dye visible on an x-ray and monitoring an x-ray during the injecting to verify effusion.

7. The method of claim 1, further including the step of introducing a pacemaker electrode through the sheath into the intracardial space.

8. The method of claim 1, further including the step of introducing a defibrillation electrode through the sheath into the intracardial space.

9. The method of claim 1, further including the step of inserting a mapping device through the sheath into the intracardial space.

10. The method of claim 1, further including the step of inserting an ablation device through the sheath into the intracardial space.

11. The method of claim 1, further including the step of removing pericardial fluid through the sheath for culture analysis.

12. The method of claim 1, further including the step of removing a tissue sample from tissue bounding the pericardial space for tissue analysis.

13. The method of claim 1, further including the step of introducing medication through the sheath into the intracardial space.

14. The method of claim 1, further including the step of introducing a steerable device through the sheath into the pericardial space.

15. The method of claim 1, further including the steps of introducing an implantable device into the pericardial space through the sheath, and stapling the device to one of the epicardial and pericardial surfaces.

16. The method of claim 1, further including the step of creating a second perforated opening for providing a second access opening into the intracardial space.

17. The method of claim 16, further comprising introducing a pericardiascope through one of said perforated openings into the intracardial space.

18. The method of claim 1, further including the step of placing the patient under local anesthesia.

19. The method of claim 1, wherein the step of distending the pericardium comprises accessing the right subclavian vein with a puncturing and infusing device.

20. The method of claim 1, wherein the step of distending comprises accessing the left subclavian vein with a puncturing and infusing device.

21. The method of claim 1, wherein the step of distending comprises accessing the left internal jugular vein with a puncturing and infusing device.

22. The method of claim 1, wherein the step of distending comprises accessing the left external jugular vein with a puncturing and infusing device.

23. The method of claim 1, wherein the step of distending comprises accessing the left external jugular vein with a puncturing and infusing device.

24. The method of claim 1, wherein the step of distending comprises accessing the right external jugular vein with a puncturing and infusing device.

25. The method of claim 1, wherein the step of distending the pericardium comprises accessing the left cephalic vein with a puncturing and infusing device.

26. The method of claim 1, wherein the step of distending comprises accessing the right cephalic vein with a puncturing and infusing device.

27. The method of claim 1, wherein the step of distending comprises accessing the left femoral vein with a puncturing and infusing device.

28. The method of claim 1, wherein the step of distending comprises accessing the femoral vein with a puncturing and infusing device.

29. The method of claim 1, wherein the step of distending comprises accessing the right atrium with a puncturing and infusing device.

30. The method of claim 1, wherein the step of distending comprises accessing the right ventricle with a puncturing and infusing device.

31. A method of percutaneously implanting a defibrillation lead within the intrapericardial space of a patient's heart, the defibrillation lead having a distal electrode, a body, and proximal connection means capable of making electrical contact to an implantable defibrillation device, the method comprising the steps of:

distending the pericardium from the epicardium by injecting a small volume of fluid into the pericardium, so that pericardial effusion results;

percutaneously perforating the pericardium by advancing a perforation device having a lumen therethrough towards the distended pericardium until the fluid flows out of the lumen, thereby indicating that the pericardium wall has been perforated;

inserting a guide wire into the pericardium through the lumen of the perforation device until a distal end thereof is positioned within the pericardium;

enlarging the perforated opening in the pericardium by inserting an introducer over the guide wire and into the tissue; and

inserting the distal electrode of the defibrillation lead within the introducer until the distal electrode is likewise positioned within the pericardium.

32. The method of claim 31, wherein the step of distending the pericardium comprises:

transvenously attaching a screw-in catheter to the right atrial lateral wall;

advancing a stylet having a tip through the catheter until the tip contacts the atrial wall;

puncturing the atrial wall with the tip of the stylet; and

infusing the small volume of fluid through the catheter into the pericardium.

33. The method of claim 31, wherein the step of perforating the pericardium comprises:

plugging the lumen of the perforation device with a relatively rigid rod prior to inserting the perforation device,

the rigid rod preventing tissue coring as the perforation device is inserted;

inserting the perforation device and rod only until a tip of the perforation device is abutted against the pericardium;

removing the rigid rod from the lumen; and

perforating the pericardium at the point where the perforation device tip is abutted against the pericardium, thereby making an opening in the pericardium through which the perforation device tip may be inserted.

34. The method of claim 33, wherein the step of perforating the pericardium at the point where the perforation device is abutted against the pericardium further comprises inserting a cutting device into the lumen and cutting an opening through the pericardium wall using the cutting device.

35. The method of claim 31, wherein the step of inserting the guide wire into the distended pericardium comprises inserting the guide wire into the distended pericardium from a sub-xiphoid position.

36. The method of claim 31, wherein the step of inserting the guide wire into the distended pericardium comprises inserting the guide wire into the distended pericardium from an intercostal position.

37. The method of claim 31, further comprising the step of tunneling the body of the defibrillation lead to a desired tissue location, whereat the proximal connection means of the defibrillation lead may be connected to a desired defibrillation device.

38. The method of claim 31, wherein the step of inserting the distal electrode into the pericardium further comprises the step of anchoring the distal electrode within the pericardium.

39. The method of claim 38, wherein the step of anchoring the distal electrode within the pericardium comprises the step of stimulating a fibrosis attachment site within the pericardium whereat the distal electrode may be anchored.

40. The method of claim 31, wherein the defibrillation lead comprises a deployable defibrillation lead having a retracted position wherein the distal electrode thereof is maintained in a retracted position, and a deployed position wherein the distal electrode is extended so as to provide a larger electrode surface area, and further wherein the step of inserting the distal electrode of the defibrillation lead comprises inserting the distal electrode through the introducer while in its retracted position and extending the distal electrode to its deployed position after the distal electrode has been inserted within the pericardium.

41. A method of positioning at least one defibrillation lead within the pericardium of a mammal, the defibrillation lead having deployable distal electrode means for selectively placing an electrode in contact with a desired tissue area when the electrode is deployed, and for selectively maintaining the electrode in a retracted position, thereby facilitating the movement and positioning of the electrode

until the electrode is positioned at a desired tissue location, the method comprising the steps of:

(a) injecting a fluid between the heart and the pericardium, thereby extending the pericardium away from the heart;

(b) percutaneously inserting a guide wire having a lumen therethrough into the extended pericardium at a desired tissue contact location until the fluid injected between the heart and the pericardium flows out of the lumen, thereby indicating that the pericardium wall has been perforated;

(c) placing a sheath introducer into the pericardium over the guide wire;

(d) inserting the electrode, in its retracted position, within the pericardium through the sheath introducer; and

(e) deploying the electrode within the pericardium, whereby the electrode makes contact with a large tissue area at the desired tissue contact location within the pericardium.

42. The method of claim 41, wherein the step of injecting a fluid between the heart and the pericardium comprises:

transvenously attaching a screw-in catheter to the right atrial lateral wall of the heart;

advancing a stylet through the catheter until a tip of the stylet contacts the atrial wall;

puncturing a small hole in the atrial wall with the tip of the stylet; and

injecting the fluid through the catheter and through the punctured hole in the atrial wall into the space between the heart and the pericardium.

43. The method of claim 41, wherein the step of percutaneously inserting the guide wire comprises inserting the guide wire into the distended pericardium from a sub-xiphoid position.

44. The method of claim 41, wherein the step of deploying the electrode further comprises recording the ECG of said mammal to aid in correctly positioning the electrode.

45. A system for implanting a defibrillation lead in a mammal, the mammal having a heart surrounded by a pericardium, the system comprising:

a defibrillation lead having a deployable distal electrode that selectively assumes a retracted position adapted to promote the positioning of the distal electrode without having the distal electrode becoming entangled with body tissue, and an extended position adapted to promote contact with body tissue over a large area, the defibrillation lead having deployment means for extending the distal electrode to its extended position;

means for injecting a fluid between the heart and the pericardium, thereby extending the pericardium away from the heart;

a perforation device having a lumen therethrough, the perforation device being sub-xiphoidally inserted toward the extended pericardium until the fluid flows out of the lumen, thereby indicating that the extended pericardium wall has been perforated; and

insertion means for inserting the defibrillation lead, with its deployable distal electrode in its retracted position, into the pericardium until the distal electrode is positioned at a desired location within the pericardium.

46. The system of claim 45, wherein the defibrillation lead comprises anchoring means for anchoring the distal electrode to the body tissue.

47. The system of claim 45, wherein the perforation device comprises:

a blunt needle having a removable, rigid rod therethrough, the rod being capable of preventing tissue coring as the needle is advance into the pericardium.

48. A defibrillation lead system comprising:

a sheath;

means for passing said sheath through a pericardium surrounding a heart from a percutaneous position;

a defibrillation lead having a distal electrode, said defibrillation lead being of a size that allows it to be slidably inserted through said sheath until said distal electrode resides within the pericardium; and

means for anchoring said distal electrode to a desired location within the pericardium, said anchoring means comprising means for stimulating a fibrosis attachment site.

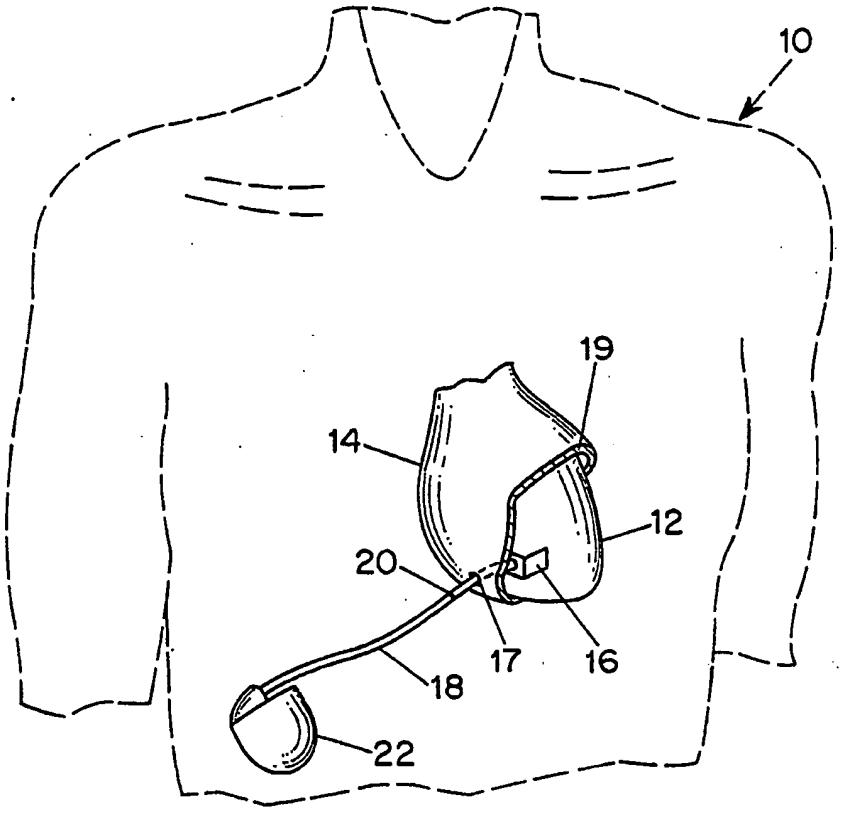


FIG. 1

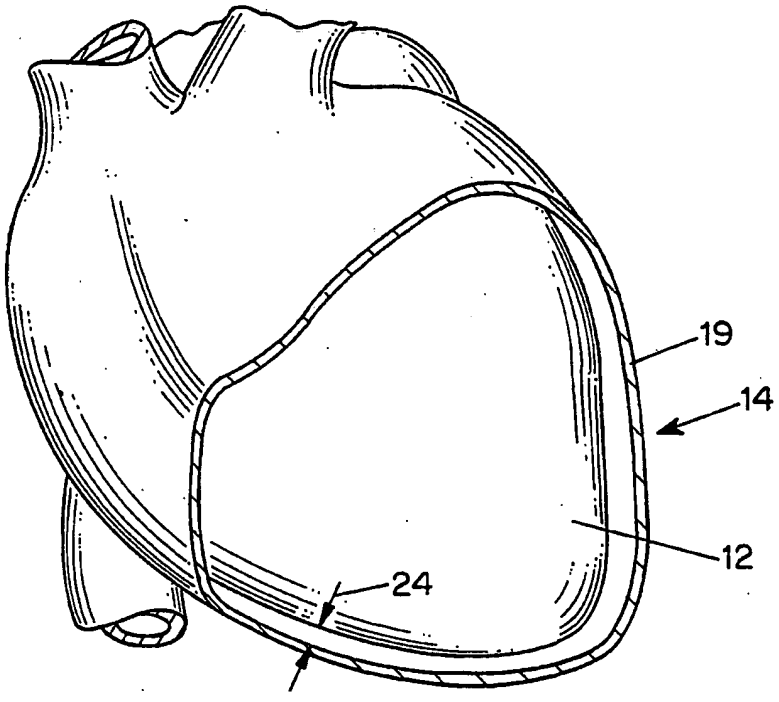


FIG. 2A

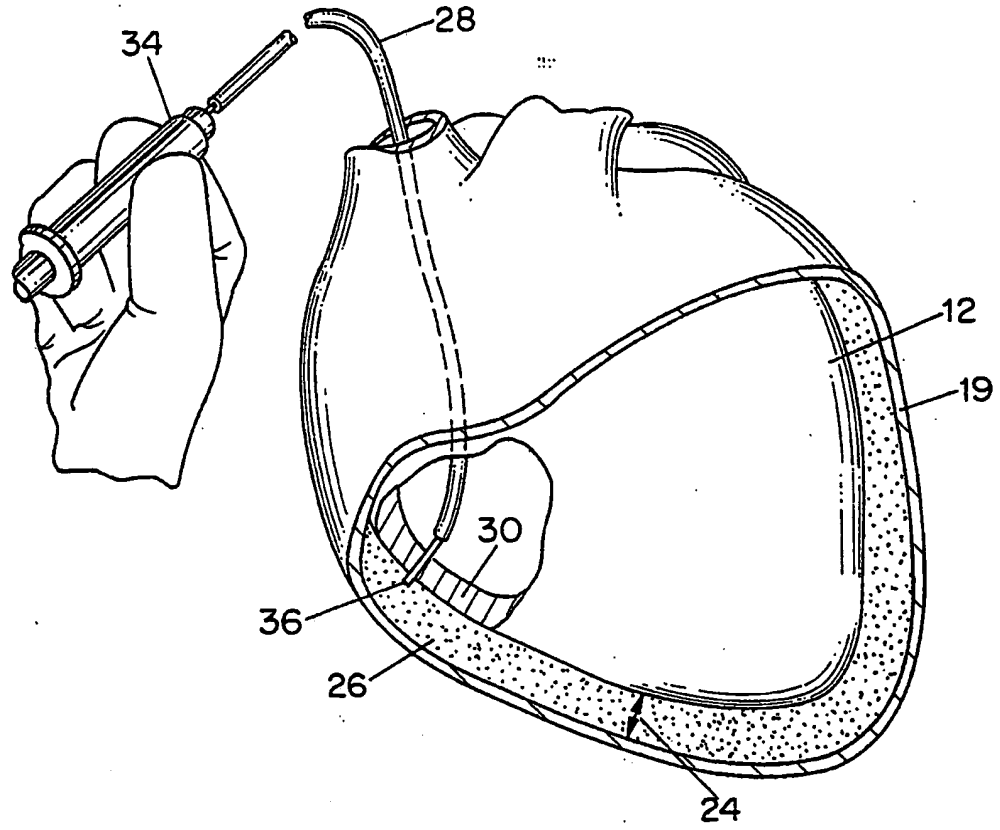


FIG. 2B

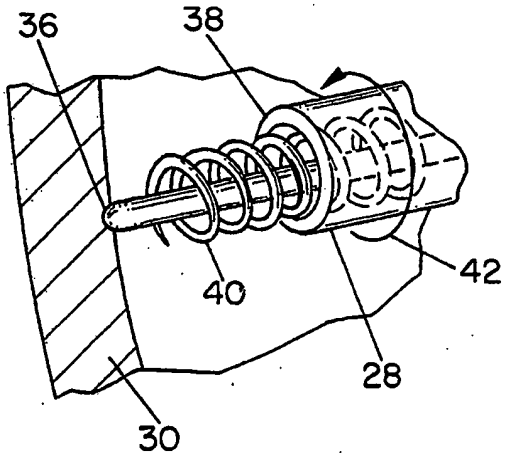


FIG. 3A

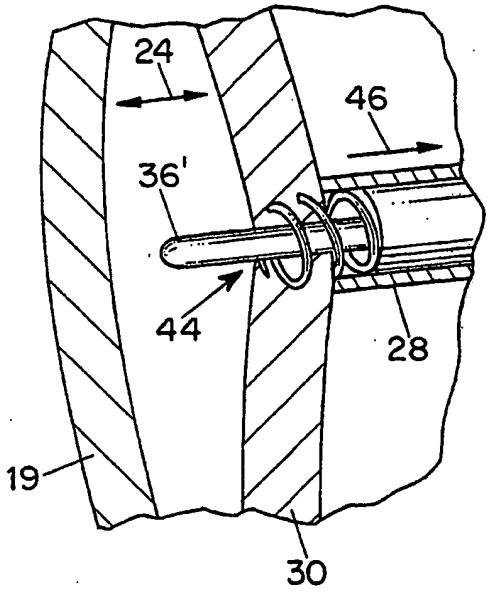


FIG. 3B

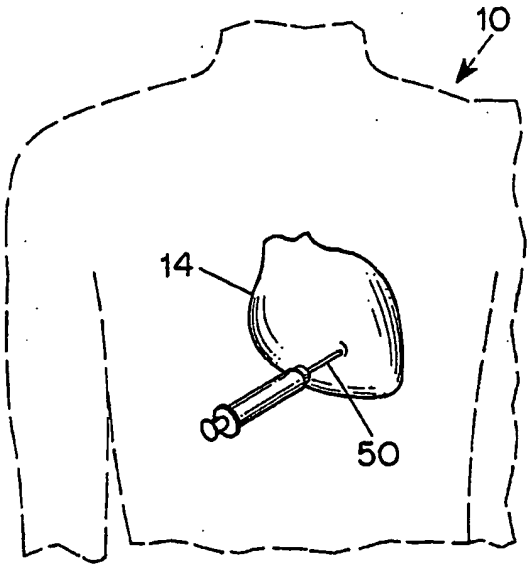


FIG. 4

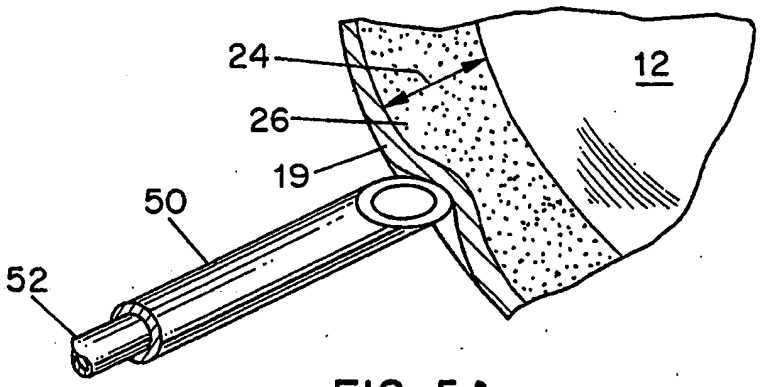


FIG. 5A

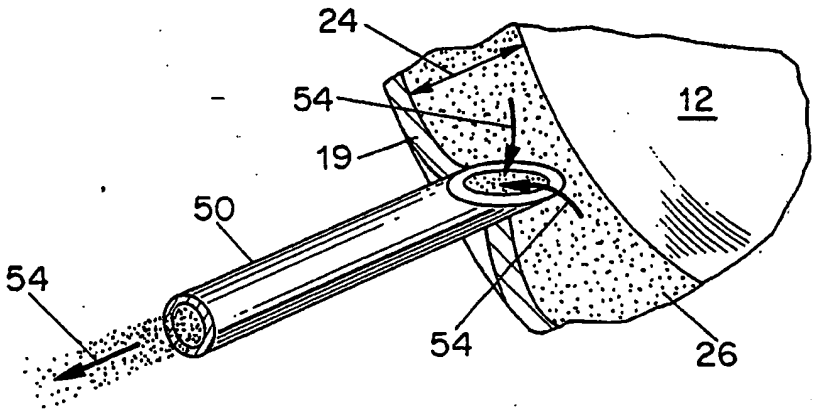


FIG. 5B

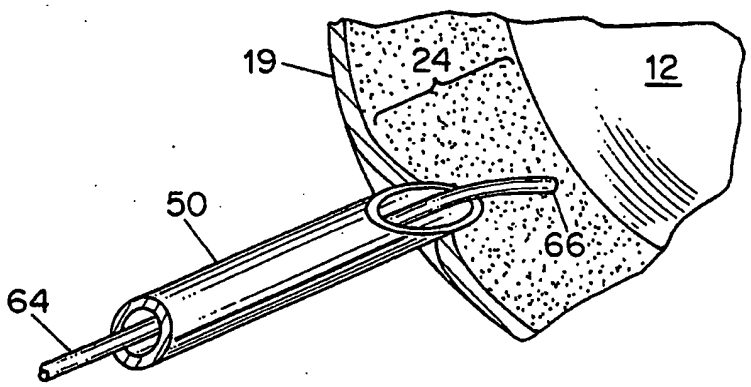


FIG. 6A

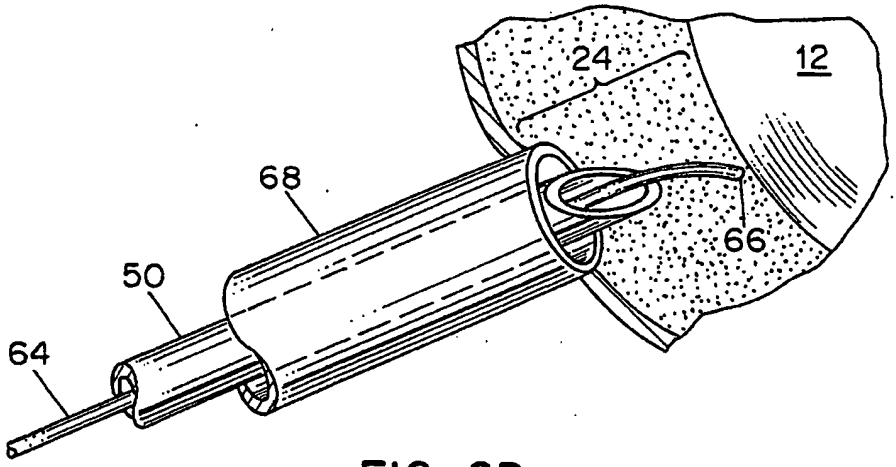


FIG. 6B

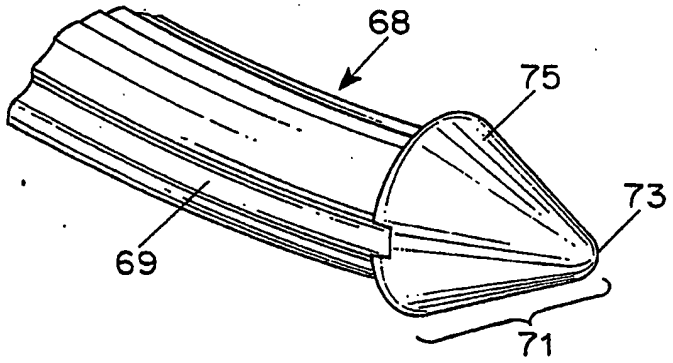


FIG. 6C

# INTERNATIONAL SEARCH REPORT

International application No.
PCT/US93/00693

**A. CLASSIFICATION OF SUBJECT MATTER**

IPC(5) :A61N 1/05
US CL :128/784
According to International Patent Classification (IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 128/785,

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|---|---|---|
| X<br>Y | US,A, 4,991,578 (Cohen) 12 February 1991, See entire document. | 1-48<br>48 |
| X | US,A, 4,865,037 (Chin et al.) 12 September 1989, See entire document. | 48 |
| A | US,A, 4,946,457 (Elliott) 07 August 1990, See abstract (Elliott et al.) | 1-48 |
| A | US,A, 4,884,567 (Elliott et al.) 05 December 1989, see abstract. | 1-48 |

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

| | | | |
|---|---|---|---|
| * | Special categories of cited documents: | "T" | later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention |
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| "E" | earlier document published on or after the international filing date | "Y" | document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art |
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| "O" | document referring to an oral disclosure, use, exhibition or other means | | |
| "P" | document published prior to the international filing date but later than the priority date claimed | | |

| | |
|---|---|
| Date of the actual completion of the international search<br>15 APRIL 1993 | Date of mailing of the international search report<br>17 MAY 1993 |
| Name and mailing address of the ISA/US<br>Commissioner of Patents and Trademarks<br>Box PCT<br>Washington, D.C. 20231<br>Facsimile No. NOT APPLICABLE | Authorized officer<br>SCOTT GETZOW<br>Telephone No. (703) 308-2997 |

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